CASE STUDY

LIFECYCLE MANAGEMENT

Support for the preparation and submission of Marketing Authorisation Transfer Applications in over 20 European countries

BlueReg was engaged to assist a biopharmaceutical company based in France with the preparation and the submission of transfer of marketing authorisation applications for a product authorised through the Mutual Recognition Procedure.

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Challenges

Unlike marketing authorisation (MA) applications and variation procedures, there is no harmonised system for the transfer of a marketing authorisation from one marketing authorisation holder (MAH) to another within the European Union. The MA transfer has to be handled as a purely national application according to national rules, which may greatly differ among member states.

The main challenge was meeting the tight timelines (3 months) for the collection of the country-specific requirements, the coordination of the preparation and submission of MA transfer application dossiers in more than 20 member states.

BlueReg support

BlueReg put in place a dedicated team of consultants with individual expertise allowing to meet the regulatory requirements and client's expectations.

The following support was provided:

- Collection of the regulatory requirements and timelines for each member state

- Close collaboration with local Regulatory Affairs affiliates or partners

• to confirm the content, the structure and the submission format (paper or electronic) of the submission package

• to confirm the need for publishing or not

• to confirm the estimated timelines for submission and approval of the MA transfer application

• to ensure that the requested documents for which they are responsible are provided in a timely manner and in the dedicated storage location

• to ensure that they review and approve the submission package prior to publishing (if applicable)

• to confirm the local submission dates and provide support in case of validation questions from Competent Authorities

- Quality Check (QC) and cleaning of the client's regulatory database to ensure that the product information (registrations & lifecycle records) to be provided to the new MAH is complete and accurate.

Achievements

- Submission of MA transfer in each concerned member state in accordance with agreed timelines.

- The client was thankful for BlueReg support and commitment throughout the application process and acknowledged BlueReg regulatory expertise on MA transfer.

For more information please contact us

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